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BY CM/ECF AND HAND DELIVERY
The Honorable Richard G. Andrews
United States District Court
844 N. King Street
Wilmington, DE 19801

Re: *United Therapeutics Corporation v. Liquidia Technologies, Inc.* C.A. No. 23-975-RGA

Dear Judge Andrews,

Liquidia Technologies, Inc. ("Liquidia") respectfully responds to United Therapeutics Corp.'s ("UTC") Court Ordered letter regarding the construction of "a/the" in the '327 patent's asserted claims. UTC's letter (D.I. 133), does not comply with the Court's September 30, 2024 Order to provide clarity and instead perpetuates the ambiguity it seeks to present at trial.

As the Court indicated, "a/the" would be construed as "one or more[,]" but that this construction "leaves too much wiggle room in for the Plaintiff[.]" (*See* 9/30/24 *Markman* Tr. at 22:7-13.) Accordingly, the Court required UTC to submit a letter indicating for each claim "where the context clearly dictates otherwise[, and] [p]resumably from context, it's that it's singular." (*Id.*) The Court went on to say that "at the end of the day, the construction ***will not be*** 'one or more unless the context dictates otherwise' because we'll know which ones the context dictates otherwise. **So it will be fixed**." (*Id.* at 22:20-23 (emphasis added).)

UTC's letter does not identify in which claims "a/the" means "one" and in which claims it means "more than one." (*See* D.I. 133.) UTC simply states that "a/the" mean "one patient" in "circumstance[s] where the phrase 'a patient' is applied to a single patient." (*Id.*) UTC's circular reasoning does nothing to limit the "wiggle room" the Court noted and Liquidia is concerned about.

Dependent claims 2, 4, 6, 7, 8 (through its dependency from claim 7), 9, and 10 (through its dependency from claim 9), all require achieving a "statistically significant" increase, reduction, or improvement in a specified outcome. (Ex. D.I. 94-1, Ex. B at cls. 2, 4, 6, 7, 8, 9, 10.) The '327 patent's specification describes how the inventors determined whether a "statistically significant" outcome was achieved: treating a sufficient number of patients to obtain an outcome that would support a statistical analysis. (*See id.* at 31:9-37.) The primary endpoint, change in the 6-minute walk distance test, was statistically analyzed to obtain a confidence interval. (*Id.* at 31:29-32:9, Fig. 4, Fig. 6, Table 5.) The secondary endpoints were also statistically analyzed. (*Id.* at 33:35-47, 34:34-47, Fig. 1, Fig. 7, Table 5.) The intrinsic evidence unequivocally establishes that claims requiring a "statistically significant" outcome cannot be met by treating a single patient. The extrinsic evidence is consistent, as UTC's expert, Dr. Nathan, testified that a "statistically significant" result cannot be achieved by treating a single patient. (D.I. 123 at 17; D.I. 124, Ex.

19 at 71:9-72:3.) Accordingly, "a/the" in claims 2, 4, and 6-10 cannot be "fixed" as a singular patient, but instead are literally directed to more than one patient.

"A/the" in claim 1 as it pertains to a "patient" or "maximum tolerated dose" ***cannot be limited only to the singular "one,"*** as that would render dependent claims 2, 4, and 6-10 invalid for improper dependency. Thus, to the extent the Court has made its determination that "a/the" means "one or more" and not "one and more than one" as Liquidia asserts, Liquidia states that "a/the" in claim 1 should be construed as "one or more," permitting treatment of a single patient or more than a single patient. Finally, based on their dependency on claim 1, "a/the" in claims 3, 5, 11, and 14-19, means a "singular" patient or inhalation device.

Respectfully submitted,

/s/ Nathan R. Hoeschen

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cc: Clerk of Court (via CM/ECF & Hand Delivery)
All Counsel of Record (via CM/ECF & Email)